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UV Spectrophotometeric Analytical Method Development and Validation for the Determination of Telmisartan in Pharmaceutical Drug and Drug Formulation (Tablet Dosage Form)

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ABSTRACT

An easy, simple, specific, speedy, precise and accurate have been developed and validated for content determination of Telmisartan. This article based on validation of analytical method procedures which is established in ICH Q_2 (R1).Telmisartan demonstrated the absorption maxima in at 291.2 nm and found was linear for a range of 5 µg/ml –25 µg/ml with correlation coefficient (LOD) of Telmisartan was found to be 2.09µg/ml and the limit of quantification (LOQ) of Telmisartan was found to be 6.34 µg/ml. The analytical method validation of the above proposed method was performed by carrying out precision and accuracy studies. The Accuracy percentage recovery on three different levels i.e. 25%, 50% and 75% was found to be 95.20%, 94.21% and 90.95% respectively. The proposed analytical method demonstrated good Intra precision (Repeatability) with relative standard deviations 2.54. The proposed analytical method was validated for the test parameter Specificity, Precision, Linearity and range, Ruggedness, Accuracy and recovery. The proposed method for content determination of Telmisartan in pure& tablet dosage form by UV spectrophotometer in pharmaceutical found easy, simple, accurate, precise and reproducible, economical and can be applied for the everyday quality control analysis.

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INTRODUCTION

Telmisartan is 2-(4-{[4-methyl-6-(1-methyl-1H-1, 3-benzodiazol-2-yl)-2-propyl-1H-1, 3-benzodiazol-1-yl]methyl}phenyl) benzoic acid. It is an angiotensin II receptor antagonist (ARB) used in the management of hypertension & to lower the risk of heart attacks. It relaxes blood vessels by blocking the action of a chemical that usually makes blood vessels tighter.

Literature survey reveals that few analytical methods are available including HPTLC, HPLC, and UV Spectrophotometry. Spectrophotometry is generally preferred especially by small-scale industries as the cost of the equipment is less and the maintenance problems are minimal. The method of analysis is based on measuring the absorption of a monochromatic light by colorless compounds in the near ultraviolet path of spectrum (200-380nm).

UV-Vis spectroscopy is an analytical technique that measures the amount of discrete wavelengths of UV or visible light that are absorbed by or transmitted through a sample in comparison to a reference or blank sample. In this present work of drug analysis, the double beam UV spectrophotometer was used.

MATERIAL AND METHODS

INSTRUMENTATION AND MATERIALS

UV visible double beam spectrophotometer (systronics, 2202 PC) with spectra treat software having path length 1 cm UV matched quartz cells was used. Telmikind – 20 mg Tablet (Telmisartan Tablet IP 20 mg, manufacture by mankind pharmaceuticals) sample procured from market and Telmisartan standard from nanoceut pharmaceutical, Pondicherry. All chemical used such as solvent Sodium chloride from nice pharmaceutical (P) LTD, Kochi.

PRELIMINARY SOLUBILITY STUDIES OF DRUGS

Around 25mg of Telmisartan was weighed and solubility was checked in water, methanol, ethanol, 0.1 HCl, 0.1 M NaOH. The drug was found to be soluble in 0.1M NaOH.

PREPARATION OF 0.1M NaOH SOLUTION

Transferred about 300 ml of water to the 1000 ml volumetric flask, the slowly added about 4 gm of Sodium Hydroxide with continuous stirring then add distilled water up to mark the volume of 1000 ml, mixed the solution thoroughly resulting 0.1 M NaOH, This solution is used as diluent.

PREPARATION OF STANDARD SOLUTION

Weighed accurately about 100 mg of Telmisartan and transferred to 100 ml amber volumetric flask. Dissolved in diluent and made up the volume to 100 ml, further transferred 1 ml of solution from previous solution to another 100 ml volumetric flask and make it up to 100 ml using 0.1 NaOH for get a concentration 10 µg/ml.

SELECTION OF WAVELENGTH FOR ANALYSIS OF TELMISARTAN

The standard solution having concentration 10µg/ml was scanned at 200 nm to 350 nm with diluent as the blank to detect maximum wavelength

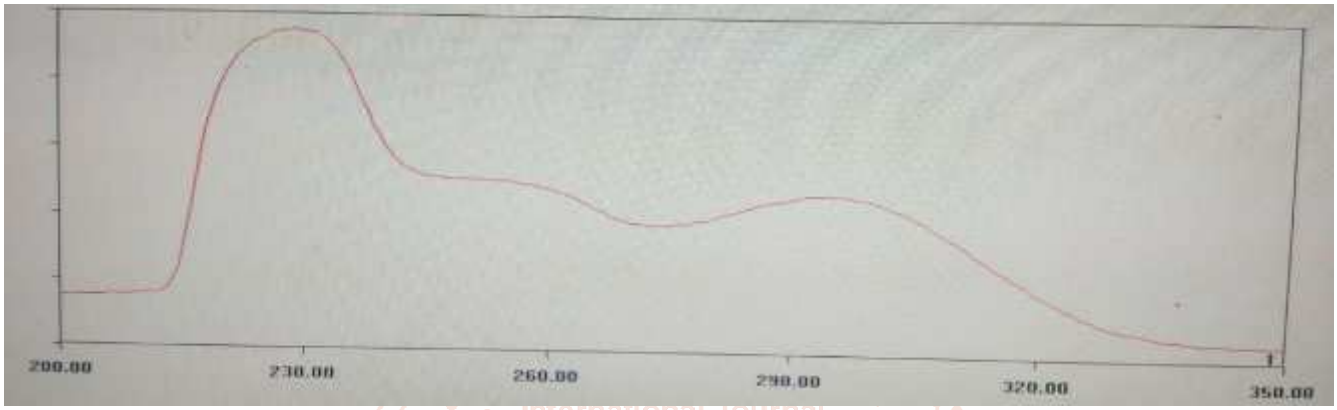

Fig 3 Estimation of Maxima of Telmisartan

From the above (**Fig 3**) spectra of Telmisartan wavelength maxima was identified as 291.2 nm (λmax).

VALIDATION OF PROPOSED ANALYTICAL METHOD

Analysis of variance was used to ensure the validity and performance effectiveness of the proposed analytical methods.

SPECIFICITY

Specificity is the capacity to appraise obviously the analyte in the existence of components which could be predictable to be present. In general these might consist of impurities, degradants, matrix, etc. Specificity was performed by scanning of diluent solution and Telmisartan Standard solution of concentrations 10 µg/ml, 15 µg/ml and 20 µg/ml in spectrophotometric range from 200 nm to 350 nm to substantiate specific absorption maxima at predefined wavelength i.e. 291.2 nm and solution stability study executed to assess the solution stability at different time interval up to 26 hrs.

INSTRUMENT PRECISION

Instrument precision was carried out to assess the suitability of the developed analytical method with respect to capacity of instrument consistency to afford the precise wavelength maxima when scanned the Telmisartan Standard solution of having concentrations 10 µg/ml in the UV range from 200 nm to 350 nm. To make sure specific absorption maxima at predefined wavelength 291.2 nm with reproducible absorption detection. Five separate standard preparations were scanned / analyzed according to the proposed analytical method of analysis. The % RSD due to Telmisartan concentration for the five standards was found 2.182%.

Table 1 Instrument precision

S. No	Standard number	Absorbance at 291.2 nm	%RSD
1	Standard preparation 1	0.427	
2	Standard preparation 2	0.427	
3	Standard preparation 3	0.410	2.182
4	Standard preparation 4	0.431	
5	Standard preparation 5	0.414	
Average absorbance		0.421	

LINEARITY AND RANGE

The linearity of an analytical method is the ability to elicit test results, which are directly proportional to the concentrations of drug in a given range. Linearity justifies the use of single calibrations. The correlation coefficient of the Regression line for was found that 0.996.

Three levels of five different concentrations of Telmisartan Standard solution with concentrations range from 5µg/ml, 10µg/ml, 15µg/ml, 20µg/ml and 25µg/ml, in the range relative to the working concentrations, were prepared and recorded the absorbance as per proposed method of analysis. A linear regression curve was drawn, the correlation coefficient (R2) and assessment value calculated. The Correlation coefficient (R2) for Telmisartan obtained is 0.996.

Table 2 Linearity and Range

S. No	Standard Concentration (µg/ml)	Absorbance at 291.2 nm	Correlation coefficient
1	5	0.263	0.9965
2	10	0.486	
3	15	0.656	
4	20	0.823	
5	25	0.995	

The plot is a straight line and the results are tabulated in the **Table 2** and curve is shown in the **figure 4.**

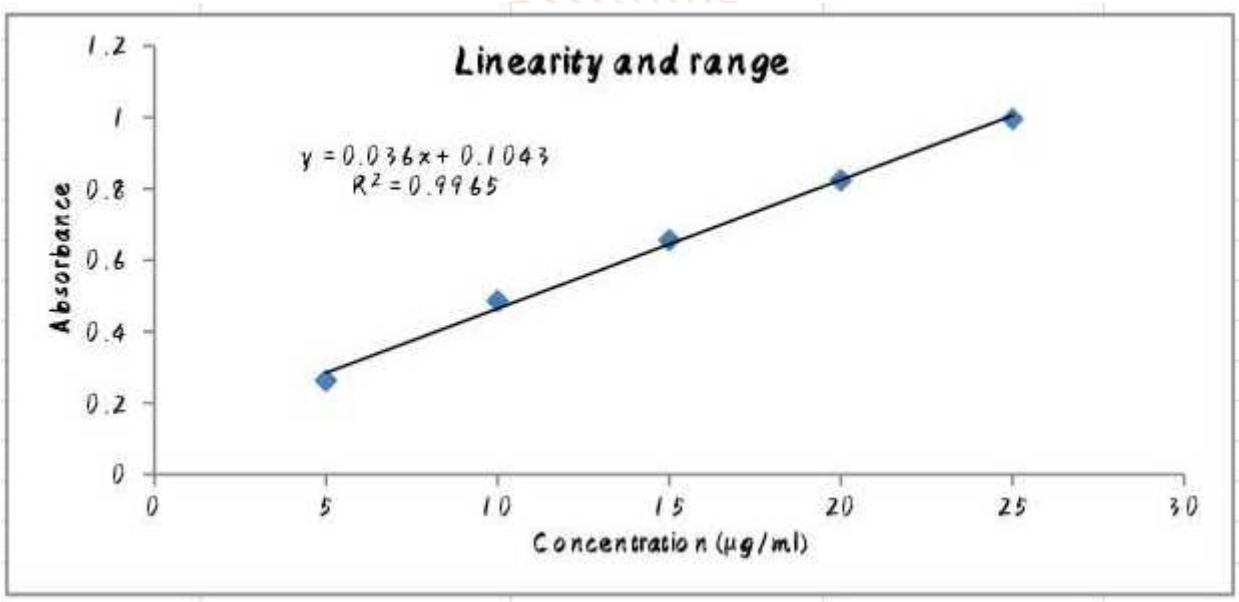

Figure 4 Linearity and range of Telmisartan

LIMIT OF DETECTION &LIMIT OF QUANTITATION

For determination of Limit of Detection and Limit of quantification assessed Telmisartan Standard solution (n= 3) through concentration's range from 5µg/ml, 10µg/ml,15µg/ml, 20µg/ml and 25µg/ml, considering the relative range of the working concentrations followed by the slope ratio Limit of detection of Telmisartan were found to be 2.09 µg/ml and Limit of Quantitation of Telmisartan were found to be 6.34 µg/ml. Results are reported in Table 3.

Table 3 LOD & LOQ of Telmisartan

S. No	Sample	LOD (µg/ml)	LOQ (µg/ml)	Linearity Range (µg/ml)	Calibration equation	±SD
1	Sample A	1.88	5.69	5 -25	0.036x+0.1043	0.25
2	Sample B	2.12	6.44	5 - 25	0.031x+0.0911	0.24
3	Sample C	2.27	6.89	5 - 25	0.031x+0.0662	0.28

ANALYTICAL METHOD PRECISION

The precision of an analytical method expresses the degree of conformity surrounded by individual test results when the method is applied to multiple sampling of a homogenous sample.

METHOD OF ANALYSIS FOR TABLET FORMULATION

50 mg equivalent weight of tablet powder was transferred to 100 ml amber volumetric flask. Dissolved in about 70 ml of diluent, Sonicated for 20 minute with intermittent shaking and made up the volume to 100 ml with diluent. The solution was filtered through Whatmann filter paper, discarding first few ml of filtrate, and further transferred 2 ml of solution to 100 ml amber volumetric flask and made up to 100 ml of Solution with 0.1 NaOH.

ASSAY/PRECISION (REPEATABILITY)

This parameter determines the repeatability of Telmisartan tablet 20 mg assay results under the same operating conditions over a short period of time.

The % RSD for Telmisartan Tablet 20 mg concentration for the five samples was found to be 2.54%. Five separate samples preparation were analyzed according to the proposed method of analysis. Results are tabulated in the Table 4.

Table 4 Intraday precision (Repeatability)

20 mg of Telmisartan tablet

S. No	Sample no	Assay content in (mg)	%Assay content	±SD	%RSD
1	Sample 1	20.00	100.0		
2	Sample 2	20.00	100.0		
3	Sample 3	19.49	97.39	2.47	2.54
4	Sample 4	19.35	96.65		
5	Sample 5	18.88	94.12		
	Average % assay	19.54	97.63		

ACCURACY

This parameter determines the accuracy of the assay results under the same operating conditions. A Telmisartan Tablet 20 mg sample was analyzed for the accuracy with known quantity of standard samples of Telmisartan at 25%, 50%, 75% concentration levels and assayed as per the method stated under proposed analytical methods respectively. Three determinations were performed under each concentration levels respectively. Results are shown in Table 4, 5, 6.Telmisartan at 25%, 50%, 75% concentration was found to be 3.36%, 3.17% and 1.57% respectively. Nine sample preparations were analyzed according to the proposed method of analysis. The %RSD due to Telmisartan Tablet 20 mg concentration for the assay meets the requirement and accuracy of recovery is within 90.0% to 110%. Results are Tabulated in the Table 5, 6 & 7

Table 5 Accuracy and Recovery reported at 25 % Conc levels

20 mg of Telmisartan tablet

S. No	Accuracy at 25% level	Amount of pure drug added (mg)	Total amount of drug in theoretical value (mg)	Experimental value (mg)	% assay content	±SD	%RSD
1	Sample A	5	25	24.6	98.40		
2	Sample B	5	25	23.8	95.20	3.20	3.36
3	Sample C	5	25	23.0	92.00		
			Average	23.8	95.20		

Table 6 Accuracy and recovery reported at 50% Conc levels.

20 mg of Telmisartan tablet

S. No	Accuracy at 50% level	Amount of pure drug added (mg)	Total amount of drug in theoretical value (mg)	Experimental value (mg)	% assay content	±SD	%RSD
1	Sample A	10	30	29.3	97.60		
2	Sample B	10	30	27.8	92.66	2.98	3.17
3	Sample C	10	30	27.8	92.33		
			Average	28.3	94.21		

Table 7 Accuracy and Recovery reported at 75% conc levels
20 mg of Telmisartan tablet

S. No	Accuracy at 75% level	Amount of pure drug added (mg)	Total amount of drug in theoretical value (mg)	Experimental value (mg)	% assay content	±SD	%RSD
1	Sample A	15	35	32.4	92.60		
2	Sample B	15	35	31.8	90.85	1.59	1.75
3	Sample C	15	35	31.3	89.42		
			Average	31.8	90.95		

SOLUTION STABILITY

Solution stability of the Telmisartan Tablet 20 mg sample Solution was performed up to 26 hrs with different time Interval and found the solution is stable showing cumulative % RSD of different time interval is 1.081 which is less than the 2. Hence the Telmisartan Tablet 20 mg sample solution is found stable up to 26 hrs at room temperature and recommended for 24 hrs solution stability (%RSD 0.789).

RESULTS ANS DISCUSSION

The proposed method in the presented work provides an easy, simple, stable, precise, reliable, rapid, less expensive (Economical), time saving and convenient method for the analysis of Telmisartan Tablet formulation using U.V spectrophotometer. λ max selected for quantitation was 291.2 nm. In this analytical method, the linearity was observed from range of 5 – 25µg/ml with R2 value of 0.9956

Method precision for the Telmisartan Tablet 20 mg at concentrations level 10µg/ml was found in the range of94 – 100 %. Accuracy of the proposed method was ascertained by recovery studies and the results were expressed as percent recovery and were found in the range of 90.95 – 95.2 %values of standard deviation and coefficient of variance was satisfactorily indicating the accuracy of the method. Intra-day and Inter-day precision studies were carried out by analyzing the sample of Telmisartan Tablet 20 mg at different time interval on the same day and on different days respectively.

Based on the outcome of analytical method development and analytical validation study test results, it was found that, the proposed analytical method for determination of Telmisartan and Telmisartan Tablet 20 mg by UV Spectrophotometry is accurate, precise, reproducible, stable, easy, simple, rapid, time saving and less expensive (Economical). The analytical method can be employed for routine analysis in quality control of Telmisartan pure drug (API) and Telmisartan formulation in pharmaceutical industry**.**

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